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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,760	09/27/2005	Anders Ljunggren	133087.09/001	3784
52286	7590	04/13/2009	EXAMINER	
Pepper Hamilton LLP 400 Berwyn Park 899 Cassatt Road Berwyn, PA 19312-1183			THOMAS, TIMOTHY P	
			ART UNIT	PAPER NUMBER
			1614	
			MAIL DATE	DELIVERY MODE
			04/13/2009 PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/550,760

Applicant(s)

LJUNGGREN ET AL.

Examiner

TIMOTHY P. THOMAS

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) 14-16 and 21-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Claims 21-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/12/2007.

The newly introduced claims do not recite the compound currently under examination, I:4, and are therefore withdrawn.

2. This application contains claims 14-16 and 21-25 drawn to an invention nonelected with traverse in the reply filed on 9/12/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments

3. Applicants' arguments, filed 12/19/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

4. Applicant's arguments with respect to the rejection under 35 USC 103 have been fully considered but they are not persuasive:

Claims 11 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ortlepp et al. ("Inhibition of the rennin-angiotensin system ameliorates genetically

determined hyperinsulinemia"; 2002; European Journal of Pharmacology; 436: 145-150: IDS 3/25/2008 reference 1) and Yoneyama, et al. ("Cardiovascular Effects of L-158,809, a New Angiotensin Type 1 Receptor Antagonist, Assessed Using the Halothane-Anesthetized In Vivo Canine Model"; 2002; Jpn. J. Pharmacol.; 89: 193-196) in view of STN (RN 133240-46-7; 1991; accessed 9/15/2008).

Applicant argues that has somehow mistakenly asserted that it would have been prima facie obvious for one skilled in the art to administer compound 1:4 in place of irbesartan in the treatment of metabolic syndrome taught by Ortlepp; that the reason provided of the substitution of one art-recognized equivalent compound (1:4) for another (irbesartan) in terms of angiotensin II receptor antagonist activity is not consistent with the goal of the Ortlepp reference (to assess metabolic syndrome, not to assess solely cardiovascular) considering that Yoneyama does not discuss metabolic syndrome for L-158,809, let alone that the compound would be expected to have any effect on metabolic syndrome, instead the reference reports cardiovascular effects of the compound. Applicants comment that it is not understood why one skilled in the art would have been motivated to replace a compound such as irbesartan for which metabolic syndrome indices were studied with a compound such as L-158,809, albeit another angiotensin II receptor antagonist, when only cardiovascular indices are reported for L-158,809.

This argument is not persuasive. The recognition by Ortlepp that irbesartan, specifically referenced as an angiotensin II receptor antagonist (implying this property is responsible for the metabolic syndrome activity) is effective with several components of

metabolic syndrome, would have led to the expectation that the substitution of other angiotensin II receptor antagonists would also have been expected to have similar activity in metabolic syndrome as irbesartan. The fact that both compounds have the same mechanism of action, recognized in the art, would have been a sufficient motivation for the substitution. This is consistent with the acceptable rationale of MPEP 2144.06 II, Substituting Equivalents Known for the Same Purpose. In addition to the cardiovascular effects discussed by applicant, the Yoneyama reference also demonstrates reduction in blood pressure (Figure 1); high blood pressure is one of the components of metabolic syndrome specifically discussed by Ortlepp, as is the associated high cardiovascular morbidity and mortality (first paragraph of the Introduction). The position is maintained that the rationale of substitution of one compound for another with the same angiotensin II receptor antagonist would have been obvious.

Conclusion

5. No claim is allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

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/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614